



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Group Art Unit: 1633

DAC
RECEIVED
JUL 29 2003

REUSER et al.

Serial No. 10/046,180

Filed: January 16, 2002

OFFICE OF PETITIONS

For: **LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC ANIMALS**

TRANSMITTAL LETTER

Commissioner for Patents
Washington, D.C. 20231

Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- (1) Transmittal Letter;
- (2) Copy of Notice to File Missing Parts of Nonprovisional Application;
- (3) Response to Notice to File Missing Parts;
- (4) Executed Reissue Declaration;
- (5) Statement Under 37 CFR 3.73(b);
- (6) Consent of Assignee by Universiteit Leiden;
- (7) Consent of Assignee by Academic Hospital;
- (8) Consent of Assignee by Erasmus Universiteit;
- (9) Petition for 2 (two) month Extension of Time;
- (10) Request for Reconsideration and Petition to the Commissioner Under 37 CFR 1.181;
- (11) Check No. 19024 \$205.00 for 2 month Extension of Time fee; and
- (12) Check No. 19205 \$130.00 for petition fee under 37 CFR 1.181.

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account No. 14-0112.

Respectfully submitted,
NATH & ASSOCIATES PLLC

Date: July 25, 2003
NATH & ASSOCIATES PLLC
1030 15th Street N.W., 6th Floor
Washington, D.C. 20005
(202) 775-8383

By:

[Signature]
Gary M. Nath
Registration No. 26,965
Todd L. Juneau
Registration No. 40,669
Customer No. 20529



BOX MISSING PARTS-REISSUE
Attorney Docket No. 24856

RECEIVED

JUL 29 2003

OFFICE OF PETITIONS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re Application of:

Group Art Unit: 1633

REUSER et al.

Serial No. 10/046,180

Filed: January 16, 2002

For: **LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC ANIMALS**

SUBMISSION OF MISSING PARTS

Commissioner for Patents
Washington, D.C. 20231

Sir:

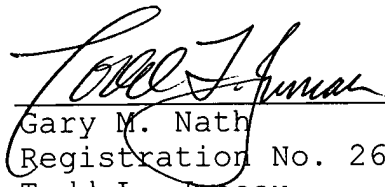
In Response to Notice to File Missing Parts of Reissue Application of March 18, 2002, submitted herewith are the following:

- (1) Executed Reissue Declaration;
- (2) Statement Under 37 CFR 3.73(b);
- (3) Consent of Assignee by Universiteit Leiden;
- (4) Consent of Assignee by Academic Hospital;
- (5) Consent of Assignee by Erasmus Universiteit;
- (6) Petition for 2 (two) month Extension of Time;
- (7) Request for Reconsideration and Petition to the Commissioner Under 37 CFR 1.181;
- (8) Check No. 19024 \$205.00 for 2 month Extension of Time fee; and
- (9) Check No. 19025 \$130.00 for petition fee under 37 CFR 1.181.

Respectfully submitted,

NATH & ASSOCIATES PLLC

By:


Gary M. Nath
Registration No. 26,965
Todd L. Juneau
Registration No. 40,669
Customer No. 20529

Date: July 25, 2003
NATH & ASSOCIATES PLLC
1030 15th Street N.W., 6th Floor
Washington, D.C. 20005
(202) 775-8383



UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231
www.uspto.gov

Paper No. 8

RECEIVED

JUL 29 2003

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OFFICE OF PETITIONS

MAR 31 2003

In re Reissue Application of: :
Reuser et al. :
Re. Serial No. 10/046,180 :
Filed: January 16, 2002 :
Original Patent No. 6,118,045 :
Original Issue Date: September 12, 2000 :
For: LYSOSOMAL PROTEINS PRODUCED IN THE: :
MILK OF TRANSGENIC ANIMALS :

OFFICE OF PETITIONS

DECISION DISMISSING

PETITION and NOTICE OF

MISSING PARTS

This is a decision on the petitions under 37 CFR 1.47(a), and under 37 CFR 1.181, filed September 18, 2002.

The petition under 37 CFR 1.47 is dismissed as immaterial, and the petition under 37 CFR 1.181 to accept this reissue application in the absence of the assent of all assignees is dismissed. **NOTE THE TIME PERIOD FOR REPLY TO THE NOTICE OF MISSING PARTS INFRA.**

BACKGROUND

The above-noted '045 patent names Reuser, der Ploeg, Pieper, and Verbeet as inventors, and issued to Pharming, Leiden University, Academic Hospital, and Erasmus University, as the joint assignees of the entire interest.

The reissue application papers as filed included an unexecuted declaration and four unexecuted consents of the named assignees of the entire interest. The unsigned declaration stated that the error sought to be corrected by this reissue application is an asserted misjoinder by way of the deletion of Pieper, who, by a conveyance recorded at the USPTO, has assigned his entire rights title and interest in the '045 patent to Pharming.

On March 18, 2002, the Office of Initial Patent Examination (OIPE) mailed a Notice of Missing Parts, indicating, *inter alia*, that the consent of all assignees was present, but had not been signed by all assignees, and that the declaration was likewise unsigned by the named inventors, and that these documents had to be executed.

In reply, on September 18, 2002, applicant filed a four month extension of time, a reissue declaration signed by all the named inventors but Pieper, the written consent of Leiden University, Academic Hospital, and Erasmus University (but not by Pharming), a statement under 37 CFR 3.73(b) signed on behalf of the aforementioned assignees of the part interest (but not by Pharming), a petition under 37 CFR 1.47(a) seeking USPTO acceptance of this reissue application in the absence of Pieper's signature on the declaration, and a petition under 37 CFR 1.181 seeking USPTO processing of this reissue application in the absence of the consent of Pharming required by 37 CFR 1.172 in compliance with 37 CFR §§ 3.71(b)(2) and 3.73.

WITH RESPECT TO THE PETITION UNDER 37 CFR 1.181

Petitioner asserts that the patent technology is undergoing clinical trials, and with commendable candor notes that Pharming will lose all rights if this reissue is permitted to proceed before the USPTO. Petitioner also asserts that the signatory parties to this reissue will suffer irreparable harm if the asserted misjoinder in the patent is not corrected.

However, where a party is an owner only of a part interest in an application, that party does not have the sole right to control prosecution of the application(s). See In re Goldstein, 16 USPQ2d 1963, 1964 (Comm'r Pat. 1988; see also In re Scold, 195 USPQ 335, 335 (Comm'r Pat. 1976); Ex parte Harrison, 1925 Dec. Comm'r Pat. 122, 123 (Comm'r Pat. 1924). The procedures set forth in the regulations serve to assure that papers filed with the USPTO in an application or patent, much less papers that present an application for reissue of a patent, are submitted on behalf of the owners of the entire interest in the application(s) or patent. See Goldstein, 16 USPQ2d at 1964.

The USPTO may not consider a reissue application without the consent of the assignee of the entire interest where a named inventor in the patent is being deleted by the reissue application procedure. See 35 USC 256; 37 CFR 1.172; MPEP 1412.04; Baker Hughes v. Kirk, 921 F.Supp. 801, 38 USPQ2d 1885 (D.D.C. 1995). If all patentees and assignees agree to a proposed change of inventorship in a patent, correction can be had on application to the Commissioner. See 35 USC § 256, first paragraph, and its implementing regulation 37 CFR 1.324. However, in the event consensus is not obtained, as herein, the second paragraph of 35 USC § 256 permits redress in federal court "on notice and hearing of all parties concerned". MCV Inc v. King-Seeley Thermos Co., 10 USPQ2d 1287, 1289 (Fed. Cir. 1989). Thus it would be inappropriate for the USPTO to permit 35 USC 251 to be employed, as here sought,

to circumvent the statutory safeguards set forth in 35 USC 256. See Baker Hughes at 1892; MPEP 1412.04.

Thus, the USPTO may not permit 35 USC 251 to be employed to: (1) make an *ex parte* determination of inventorship, and (2) circumvent the statutory safeguards of 35 USC 256 involving the extinction of an inventor's (or his successor in title's) *pro rata* property right in patented claims. See Baker Hughes, supra. In the absence of Pieper's signature on the declaration and the consent of Pharming, Pieper's successor in title, this reissue application remains incomplete within the meaning of 37 CFR 1.172 and will not be placed on the roles for examination. See 37 CFR 1.53(h). Likewise, as noted in more detail below, 37 CFR 1.47 is not appropriately invoked in this instance. As such, the USPTO will not further proceed with this reissue application. See Baker Hughes, supra. Nevertheless, petitioner may seek relief under either alternate venue noted in more detail below.

WITH RESPECT TO THE IMMATERIAL PETITION UNDER 37 CFR 1.47(a):

It should be noted that 35 USC 116 and its promulgating regulation 37 CFR 1.47(a) operate to protect the property interest of a named inventor by way of USPTO acceptance of a given application in the absence of that inventor's participation in the application. See 35 USC 116 (i.e., "subject to the same rights which the omitted inventor would have had if he had been joined.")

Since petitioner admits that the purpose of this reissue application is to delete Pieper from any reissued patent that might result from this reissue application, petitioner has failed to show how the first sentences of 37 CFR 1.47(a) can be satisfied in this instance. That is, a signing inventor(s) seeking to invoke 37 CFR 1.47 must consider the non-signing inventor to be a **joint inventor**. Since the signing inventors now contend that Pieper is not and never was a joint inventor and seek to delete Pieper as a **joint inventor** and the accompanying declaration(s) does not name Pieper as a **joint inventor**, the record is not clear how this reissue "application may be made by the other inventor [Reuser, der Ploeg, and Verbeet] on behalf of himself or herself and the nonsigning inventor [Pieper]", as required by the regulation. Petitioner has further not shown, nor is it apparent, if Pieper were deleted pursuant to 37 CFR 1.47, how 37 CFR 1.172(b) can be satisfied in this instance. Rather, the latter regulation requires that any reissue patent arising from these reissue applications "will be granted to the original patentee, his legal representatives, or assigns as the interest may appear" which here is Reuser, der Ploeg, Pieper, and Verbeet as inventors,

and Pharming, Leiden University, Academic Hospital, and Erasmus University, as the assigns.

The lack of Pieper's inclusion results in the non-joinder of Pieper, and the extinction of Pharming's rights with respect to all patented claims. Consequently, under the facts of this case, Reuser, der Ploeg, Pieper, and Verbeet as inventors, and Pharming, Leiden University, Academic Hospital, and Erasmus University, cannot logically have the same rights in both the original patent and any granted reissue patent from this reissue application. But see 35 USC 116. As such, petitioner's reliance upon 37 CFR 1.47 is both untenable, and a *non sequitur*.

Where, as here, 37 CFR 1.47 is invoked by the signatory applicants as part of a proceeding to delete a non-joining inventor from an issued patent, tension arises.¹ Manifestly, if an inventor being deleted (or his successor in title) does not agree to the proposed removal, neither can join in, or approve, the filing of the reissue application. Thus, under the circumstances of this reissue application, for the USPTO to treat, much less favorably consider the petition under 37 CFR 1.47 herein, the rights of the non-signing inventor (or his successor in title) would not be protected and that property right extinguished by way of an *ex parte* proceeding without his successor in title's participation or consent. But see Baker Hughes, supra (court holding that USPTO exceeded its authority by deciding to consider via 37 CFR 1.47, without consent of patent assignee, application for reissue filed by co-assignee to remove the other assignee's property right).

ALTERNATE VENUE

Should Pieper and Pharming or any successor to its title consent

¹The Commissioner has no authority under the statute (35 USC 256) to effect a change in inventorship of a patent unless all the named inventors consent in writing. In re RCA Corp., 209 USPQ 1114 (Comm'r Pat. 1981). Pieper, or pursuant to 35 USC 100(d), his successor Pharming, as a co-patentee (and co-assignee), has a vested property right in the original patent that can be canceled, revoked, or annulled only by judicial proceedings that afford due process of law. Iowa State University Research Foundation v. Sperry Rand Corp., 444 F.2d 406, 410, 170 USPQ 374, 377 (4th Cir. 1971). The USPTO may not permit proceedings before it under the reissue statute (35 USC 256) to circumvent the statutory safeguards of 35 USC 256. See Baker Hughes, id.

to the change of inventorship, and all parties are in consensus, petitioner should seek relief under the provisions of 35 USC 256, first paragraph, and 37 CFR 1.324 by filing a request for a Certificate of Correction. See MPEP 1412.04, under the caption "Certificate of Correction as a vehicle for correcting inventorship." Note that this avenue of relief requires, by statute, the consensus of all parties for the USPTO to have jurisdiction, and this requirement of law cannot be waived by the USPTO. See MPEP 1481, under the caption "Correction of Inventor's Names" at 1400-66. (8th Ed., Aug. 2001).

In the event that the consent of both Pieper and Pharming or any successor to Pharming's title cannot be obtained, then the interested parties may wish to seek relief under the provisions of 35 USC 256, second paragraph, before a court of competent jurisdiction as opposed to seeking relief before the USPTO under 35 USC 251. See MCV, supra.

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(B)

FILING DATE GRANTED

An application number and filing date have been assigned to this application. The item(s) indicated below, however, are missing.

Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

Correction of the following is required to complete this application.

Applicants' reply filed September 18, 2002, to the Notice of Missing Parts mailed March 18, 2002, is incomplete:

Consent of the assignees is missing. 37 CFR 1.172 requires that the reissue oath/declaration be accompanied by the written consent of all assignees. Until the consent of Pharming is supplied, the oath/declaration remains defective. See MPEP 1410.01.

A COPY OF THIS NOTICE MUST BE RETURNED WITH THE REPLY.

This application is being returned to the Office of Initial Patent Examination (OIPE) to await any reply to this Notice.

Further correspondence with respect to this matter should be addressed as follows (see 68 Fed. Reg. 14335 (March 25, 2003)):

By mail: IF MAILED PRIOR TO MAY 1, 2003

Box Missing Parts
Commissioner for Patents
Washington DC 20231

or

U.S. Patent and Trademark Office
P.O. Box 2327
Mailstop Box Missing Parts
Arlington, VA 22202

IF MAILED ON OR AFTER MAY 1, 2003

Mail Stop MISSING PARTS
DIRECTOR OF THE US PATENT AND TRADEMARK OFFICE
PO Box 1450
Alexandria Virginia 22313-1450

Any questions concerning this matter may be directed to the undersigned at (703) 305-1820.

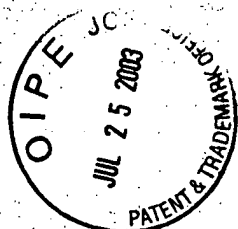


Brian Hearn
Petitions Examiner
Office of Petitions
Office of the Deputy Commissioner
for Patent Examination Policy

18. SEP. 2002 10:04

RAAD VAN BESTUUR AZR

NO. 8700 P. 2



BOX REISSUE
Attorney Docket No. 24856

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number 6,118,045

Inventor: Arnold J.J. REUSER et al.

Issued: September 12, 2000

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC
ANIMALS

REISSUE DECLARATION

We, the undersigned hereby declare that:

We are three of the four inventors named in the application which issued as the above-identified original patent. Our residences and our post office addresses, and our citizenship is given below by each of our names respectively.

Applicants believe the original patent to be partly inoperative or invalid by reason of misjoinder of inventorship in the original patent. The error relied upon is the naming of Frank R. Pieper as an inventor of the original patent. Frank R. Pieper did not invent the subject matter claimed in the original patent.

All errors which are being corrected in the present reissue application up to the time of filing of this declaration arose without any deceptive intention on the part of the applicant.

Our residences, and post office addresses are as stated below next to each of our names.

We believe we are the original, first and joint inventors of the subject matter which is described and claimed in the above-identified patent and for which this reissue application is made.

We hereby state that we have reviewed and understand the contents of the attached reissue application including the specification, and the claims.

We acknowledge the duty to disclose information which is material to the patentability of this application as defined by 37 CFR § 1.56.

We hereby appoint Gary M. Nath, Reg. No. 26,965; Harold L. Novick, Reg. No. 26,011; Todd L. Juneau, Reg. No. 40,669; Lee C. Heiman, Reg. No. 41,827; Jerald L. Meyer, Reg. No. 41,194; and Joshua B. Goldberg, Reg. No. 44,126; as our attorneys to prosecute this application and transact all business in the U.S. Patent and Trademark Office connected therewith.

Direct telephone calls to Gary M. Nath at (202) 775-8383.

18. SEP. 2002 10:04

RAAD VAN BESTUUR AZR

NO. 8700 P. 3

Send all correspondence to:

NATH & ASSOCIATES PLLC
1030 Fifteenth Street N.W.
Sixth Floor
Washington, D.C. 20005-1503

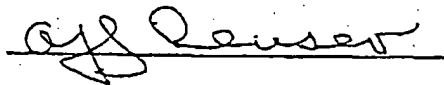
We hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent, or any reissue patent issued thereon.

A.J.J. Reuser
Arnold J.J. Reuser
Citizenship: The Netherlands
Residence:

Heemraadsingel 211A,
3023 CC Rotterdam, The Netherlands

Post Office Address:

Erasmus University Rotterdam, Office for Technology Transfer
Room EB 03, PO Box 1738
3000 DR Rotterdam, The Netherlands

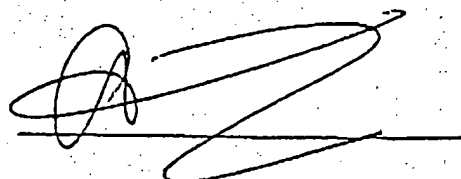


A.T. van der Ploeg
Ans T. Van der Ploeg
Citizenship: The Netherlands
Residence:

Meidoorn 27
3171 NB Poortugaal, The Netherlands

Post Office Address:

Erasmus University Rotterdam, Office for Technology Transfer
Room EB 03, PO Box 1738
3000 DR Rotterdam, The Netherlands

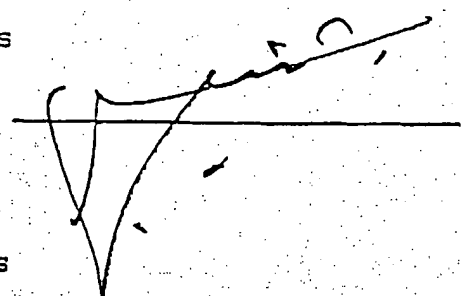


Martin Ph. Verbeet
Martin Ph. Verbeet
Citizenship: The Netherlands
Residence:

Tweede Oosterparkstraat 239
1092 BM Amsterdam, The Netherlands

Post Office Address:

Erasmus University Rotterdam, Office for Technology Transfer
Room EB 03, PO Box 1738
3000 DR Rotterdam, The Netherlands



Received: 5/16/02 1:05PM;

89090 -> Nath & Associates PLLC; Page 4

BOX REISSUE

Attorney Docket No. 24856

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number 6,118,045

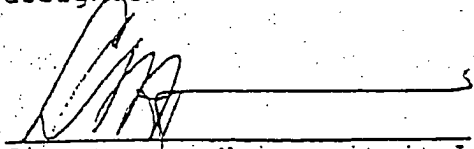
Inventor: Arnold J.J. REUSER et al.

Issued: September 12, 2000

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC
ANIMALSSTATEMENT UNDER 37 CFR 3.73(b)

THE UNIVERSITEIT LEIDEN, a University organized and existing under the laws of the country of The Netherlands, ACADEMIC HOSPITAL, a company organized and existing under the laws of the country of The Netherlands, ERASMUS UNIVERSITEIT, a University organized and existing under the laws of the country of The Netherlands, and PHARMING B.V., a company organized and existing under the laws of the country of the Netherlands, state that they are the assignees of the entire right title and interest in and to the above identified patent by virtue of assignments from the inventors based on the correction of inventorship applied for herewith, of patent application number 08/700,760 filed July 29, 1996, and which eventually matured as the above identified patent. The assignments were recorded in the United States Patent and Trademark Office on Reel _____ at Frame _____, Reel _____ at Frame _____, Reel _____ at Frame _____, and Reel _____ at Frame _____. A copy of those assignments is attached hereto.

The undersigned, whose titles are supplied below, are empowered to sign this statement on behalf of each named assignee.



Signature - Universiteit Leiden

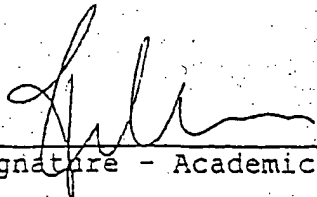
Date: March 21, 2002

L.E.H. Uredavogel
Typed or Printed Name

President
Title

Received: 5/16/02 1:05PM;

89090 -> Nath & Associates PLLC; Page 5

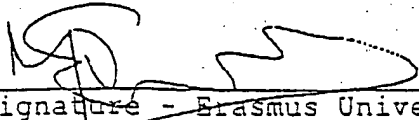


Signature - Academic Hospital

Date: April 16, 2002

F.G.A. van der Meche
Typed or Printed Name

Member Executive Board
Title



Signature - Erasmus Universiteit

Date: April 16, 2002

J.C.M. van Eijndhoven
Typed or Printed Name

President Executive Board
Title

Date: _____

Signature - Pharming B.V.

Typed or Printed Name

Title

Received: 5/16/02 1:06PM;

89090 -> Nath & Associates PLLC; Page 7

BOX REISSUE

Attorney Docket No. 24856

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number 6,118,045

Inventor: Arnold J.J. REUSER et al.

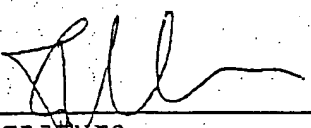
Issued: September 12, 2000

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC
ANIMALSCONSENT OF ASSIGNEE

ACADEMIC HOSPITAL, (HOSPITAL) a company organized and existing under the laws of the country of The Netherlands, which is the assignee of the entire right title and interest in and to the above identified patent by virtue of an assignment which is recorded amongst the records of the United States Patent and Trademark Office on Reel _____ at Frame _____.

HOSPITAL consents to the filing of the application for reissue of this patent.

The undersigned, whose title is supplied below, is empowered to sign this statement on behalf of the assignee.



SignatureDate: April 16, 2002F.G.A. van der Meche
Typed or Printed NameMember Executive Board
Title

BOX REISSUE
Attorney Docket No. 24856

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number 6,118,045

Inventor: Arnold J.J. REUSER et al.

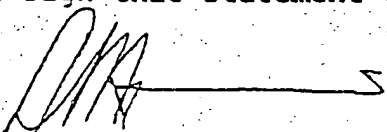
Issued: September 12, 2000

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC
ANIMALSCONSENT OF ASSIGNEE

THE UNIVERSITEIT LEIDEN, (LEIDEN) a University organized and existing under the laws of the country of The Netherlands, which is the assignee of the entire right title and interest in and to the above identified patent by virtue of an assignment which is recorded amongst the records of the United States Patent and Trademark Office on Reel _____ at Frame _____.

LEIDEN consents to the filing of the application for reissue of this patent.

The undersigned, whose title is supplied below, is empowered to sign this statement on behalf of the assignee.



Signature

Date: March 21, 2002

L.E.H. Uredlevcoogd
Typed or Printed Name

President
Title

BOX REISSUE

Attorney Docket No. 24856

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Number 6,118,045

Inventor: Arnold J.J. REUSER et al.


Issued: September 12, 2000

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC
ANIMALSCONSENT OF ASSIGNEE

ERASMUS UNIVERSITEIT, (ERASMUS) a University organized and existing under the laws of the country of The Netherlands, which is the assignee of the entire right title and interest in and to the above identified patent by virtue of an assignment which is recorded amongst the records of the United States Patent and Trademark Office on Reel _____ at Frame _____.

ERASMUS consents to the filing of the application for reissue of this patent.

The undersigned, whose title is supplied below, is empowered to sign this statement on behalf of the assignee.



SignatureDate: April 16, 2002J.C.M. van Eijndhoven

Typed or Printed NamePresident Executive Board

Title



RECEIVED
BOX MISSING PARTS-REISSUE
Attorney Docket No. 24856
JUL 29 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

OFFICE OF PETITIONS

In Re Application of:

Group Art Unit: 1633

REUSER et al.

Serial No. 10/046,180

Filed: January 16, 2002

For: **LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC ANIMALS**

REQUEST FOR RECONSIDERATION OF PETITION UNDER
37 C.F.R. § 1.181 TO THE COMMISSIONER

Applicants, who have sufficient proprietary interests in the above captioned reissue application, submit this request for reconsideration of the Commissioner's decision to dismiss the petition under 37 C.F.R. 1.181 filed September 18, 2002 requesting that a lack of consent of all Assignees be accepted for this reissue application. This reissue application seeks to correct the inventorship of U.S. Patent 6,118,045.

Statement of Facts:

Upon personal interviews with each of the three inventors who have signed the Reissue Declaration as well as former Pharming employees, applicants through their counsel have discovered the misjoinder of the presently named inventive entity. The interviews indicated Dr. Frank R. Pieper had no role in the conception of the instantly claimed invention. Given these inventors' relative lack of experience in determining inventorship under U.S. law, and in order to be thorough and provide for the possibility that Dr. Pieper may nonetheless have been an inventor without the knowledge of the other three inventors, applicants repeatedly requested evidence of inventorship, e.g. lab notebooks, letters, etc. from Dr. Pieper. No documents were forthcoming.

Three of the named inventors proceeded to sign Reissue Declarations stating that they believe the original patent to be partly inoperative or invalid by reason of misjoinder of inventorship in the original patent. The error relied upon is that Dr. Frank R. Pieper did not invent the subject matter claimed in the original patent. This error arose without

any deceptive intention on the part of the applicants.

Further, three of the named assignees have signed Statements Under 37 CFR 3.73(b) and Consents of Assignee. These three assignees are Universiteit Leiden of the Netherlands, Academic Hospital of the Netherlands and Erasmus Universiteit of the Netherlands. The three assignees have sufficient proprietary interest in this matter.

Applicants sent the declaration for Dr. Pieper to Ms. Louise M. van den Bos of Erasmus Universiteit. Ms van den Bos, in turn, had two personal meetings with Dr. Pieper, during which he indicated he would not sign the declaration pending the outcome of negotiations between his employer Pharming Group N.V. (Pharming) who is the fourth assignee of this application, Erasmus Universiteit, and Genzyme Inc.

Pharming is the employer of Frank R. Pieper, who assigned his rights to Pharming in the original patent application number 08/700,760 for which a reissue application is being sought to correct the inventorship. It is important in this regard that Pharming is a Dutch corporation which filed for receivership protection under Dutch laws, while Genzyme Inc. is a U.S. corporation who had a relationship with Pharming and has announced their intention to acquire Pharming's assets in the press.

Pharming has refused to sign the Statement Under 37 CFR 3.73(b) and the Consent of Assignee. By refusing to sign as one of the assignees, not all of the applicants are applying for the reissue application to correct the inventorship. Remaining applicants maintain that this refusal of lack of consent is related to the refusal of the inventor Frank R. Pieper to sign the Inventors Declaration stating that is he not an inventor of U.S. Patent 6,118,045. This reissue application seeks to correct the inventorship of the original patent by revoking Frank R. Pieper as a named inventor thereof. Remaining applicants note that upon removal of Frank R. Pieper as an inventor, Pharming will lose all rights to the present inventive subject matter assigned to them by Dr. Pieper and accordingly will no longer be an assignee of this application.

The last known address of Pharming is P.O. Box 451, 2300 AL Leiden, The Netherlands.

Request for Reconsideration:

Applicants who have sufficient proprietary interest in this matter, as shown by the Statement Under 37 CFR 3.73(b) and the accompanying Consents of Assignee, thus file this request for reconsideration of the Commissioner's decision to dismiss the petition under 37 C.F.R. 1.181 filed September 18, 2002 requesting that a lack of consent of all Assignees be accepted for this reissue application seeking to list the correct inventors for U.S. Patent No. 6,118,045. Applicants would suffer irreparable damage if said patent is held to be inoperative or invalid and the reissue application correcting the inventorship is not allowed to proceed.

Applicants previously filed a Petition to the Commissioner Under 37 C.F.R. 1.181 on September 18, 2002 to allow this reissue application to be filed without the consent of the assignee Pharming. In a communication dated March 31, 2003, the Office of Petition at the USPTO indicated that the petition under 37 C.F.R. 1.181 to accept this reissue application in the absence of the assent of all assignees was dismissed.

In this regard, the Decision on Petition stated "The USPTO may not consider a reissue application without the consent of the assignee of the entire interest where a named inventor in the patent is being deleted by the reissue application procedure." The case of Baker Hughes v. Kirk, 921 F.Supp. 801, 38 USPQ2d 1885 (D.D.C. 1995) was cited in support of this decision. However, the facts of the Baker Hughes case were so significantly different from the present situation so as that this case should not be considered binding precedent on the present application. Some of these critical distinguishing features are as follows:

- 1) In the present application, a declaration executed by the three proper inventors was submitted and a copy thereof is re-submitted herewith; no such declaration was filed in the Baker Hughes case.
- 2) These three inventors provided evidence showing that Dr. Pieper was not in fact an inventor of the claimed

subject matter; no such evidence was provided in the Baker Hughes case.

- 3) In the present application, attempts were made to contact Dr. Pieper directly to give him the opportunity to present evidence showing he is in fact an inventor of the claimed subject matter; there is no evidence such an attempt was made in the Baker Hughes case.

The USPTO's reliance on the Baker Hughes case, then, does not appear to apply to the present situation.

Further, contrary to the USPTO's position, applicants have provided executed Consent of Assignee forms to the present reissue application for the Assignee of the entire interest in the claimed subject matter. As shown above, the only "rights" Pharming has as an assignee to the present invention are those it obtained from Dr. Pieper. However, in view of the sworn testimony of the other three named inventors that they were the sole inventors of the claimed subject matter, Dr. Pieper had no actual rights to this invention to convey to Pharming. Accordingly, Pharming does not actually have any rights to the claimed invention, leaving Universiteit Leiden of the Netherlands, Academic Hospital of the Netherlands and Erasmus Universiteit of the Netherlands as the assignees of entire interest to this application. Since these assignees have already consented to the Reissue application, previously filed on September 18, 2002 and a copy of which is attached herewith, the present reissue application does in fact have the consent of the assignee of the entire interest to this reissue application.

Further, applicants note that 35 U.S.C. §§ 116 and 256 permit the Commissioner to correct an error in inventorship of a patent application or a patent arising without any deceptive intention. For example, 35 U.S.C. § 116 states that:

Whenever through error a person is named in an application for patent as the inventor, or through an error an inventor is not named in an application, and such error arose without any deceptive intention on his part, the Director may permit the application to be amended accordingly, under such terms as he prescribes.

Similarly, 35 U.S.C. § 256 states that:

Whenever through error a person is named in an issued patent as the inventor, or through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

Accordingly, these sections of the U.S. Code permit the Commissioner to correct an improperly named inventorship entity upon application of all the assignees. As shown above, the assignee of the entire interest to the presently claimed subject matter has consented to the request to remove Dr. Pieper as an inventor of the present Reissue application, and the underlying U.S. Patent. Accordingly, it should be unnecessary for applicants to have to resort to filing in District Court to correct the improperly named inventorship entity.

In the alternative, applicants respectfully request the Examiner to consider this petition as a petition to suspend the rules and to obtain an equitable decision in this matter from the Commissioner. Requiring applicants to obtain the signature of an entity with no actual rights to the presently claimed invention in order to obtain a patent is both unfair and contrary to the Article 1, Section 8, Clause 8 of the Constitution of the United States, stating that "The Congress shall have power...To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." All the actual inventors, as well as the assignees of these inventors, of the presently claimed subject matter have consented to the present reissue application, filed to remove Dr. Pieper as an improperly named inventor since he had no role in the conception of this invention. Accordingly, it would be unjust to deny a patent in the presently claimed invention based on failure to obtain a signature of a non-inventor, or assignee thereof, with no actual rights to this invention.

As an additional factor in granting the petition, applicants would like to point out that this technology is currently in clinical trials

helping children in at least two locations/hospitals to be treated for Pompe's Disease, a disease which previously had a 100% fatality rate prior to this treatment. Further to this, applicants are in active licensing negotiations with organizations who will be capable of developing a product and bringing it to market. Thus, it is imperative that this petition be granted to ensure the validity of a particularly important patent.

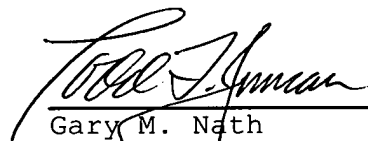
A petition fee of \$130.00 as set forth under S 1.17(h) is attached to this petition.

CONCLUSION

Applicants, who have sufficient proprietary interest in this matter, as shown by the Statement Under 37 CFR 3.73(b) and the accompanying Consents of Assignee, thus petition the commissioner to allow this reissue application to be filed without the consent of the assignee Pharming.

Any questions regarding this petition should be directed to the undersigned attorneys.

Respectfully submitted,
NATH & ASSOCIATES PLLC



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